UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte AVI J. ASHKENAZI

Appeal 2007-0866
Application 09/993,234[1]
Technology Center 1600

Decided: August 27, 2007

Before DONALD E. ADAMS, DEMETRA J. MILLS, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 34 and 36-39, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] We recognize Appellant's reference to Interference No. 105,438 which involved Appellant's Parent Application No. 08/828,683, Patent No. 6,469,144. We note that a final judgement adverse to all of the claims in Appellant's patent was entered September 26, 2006.

INTRODUCTION

"Control of cell numbers in mammals is believed to be determined, in part, by a balance between cell proliferation and cell death" (Specification 1: 23-25). One form of cell death is often referred to as "apoptosis" (Specification 1: 28-31). Various molecules, such as tumor necrosis factor-α, tumor necrosis factor-β, Apo-1 ligand (otherwise known as Fas or CD95 ligand), Apo-2 ligand have been identified as members of the tumor necrosis factor (TNF) family of cytokines (Specification 2: 26-31). A number of these molecules, [including *inter alia*,] TNF-α, TNF-β, . . . Apo-1 ligand, . . . and Apo-2 ligand "have been reported to be involved in apoptotic cell death" (Specification 2: 34-36). Appellant identified cDNA clones that encode polypeptides, which they designate as Apo-3 (Specification 8: 9-10). Appellant discloses that Apo-3 is a member of the TNFR family and is able to stimulate or induce apoptotic activity in mammalian cells (Specification 8: 11-13).

The claims are directed to a nucleic acid encoding Apo-3 polypeptide (claim 34); a vector comprising the nucleic acid (claims 36 and 37), a host cell comprising the vector (claim 38); and a process for producing Apo-3 polypeptide (claims 39). Claim 34 is illustrative:

34. Isolated nucleic acid encoding Apo-3 polypeptide comprising amino acid residues 1 to 417, 25 to 417, 25 to 198, or 338 to 417 of SEQ ID NO: 6, or a biologically active variant thereof.

The Examiner relies on the following prior art reference to show unpatentability:

Yu 6,153,402 Nov. 28, 2000[2]

The rejection as presented by the Examiner is as follows:

Claims 34 and 36-39 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Yu.

We affirm.

DISCUSSION

Claim 34 is directed to an isolated nucleic acid encoding Apo-3 polypeptide. According to claim 34, the Apo-3 polypeptide encoded by the claimed nucleic acid comprises amino acid residues:

(a) 1 to 417,

(b) 25 to 417,

(c) 25 to 198, or

(d) 338 to 417

of SEQ ID NO: 6, or a biologically active variant thereof. Accordingly, we find that claim 34 is drawn to a nucleic acid that encodes an Apo-3 polypeptide that comprises a particular sequence of amino acids, e.g., those amino acid residues corresponding to amino acid residues 25 to 198 of Appellant's SEQ ID NO: 6, or a biologically active variant thereof.

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[2] The Examiner relies on Yu's claim of priority to Provisional Application No. 60,013,285, filed March 12, 1996 (Answer 3). Accordingly, the Examiner finds that Yu's has an applicable date under 35 U.S.C. § 102(e) of March 12, 1996.

The Examiner makes the following findings of fact:

1. The claimed subject matter receives the benefit of Appellant's parent Application No. 08/710,802, filed September 23, 1996 (Final Rejection 3). Accordingly, the earliest effective filing date of the instant invention is September 23, 1996.

2. "[A]n isolated nucleic acid encoding a polypeptide comprising amino acid residues '25-198' of 'SEQ ID NO: 6' as recited in the appealed claim 34 is anticipated by the isolated nucleic acid encoding amino acids 36-209 of SEQ ID NO: 2 of . . . '285 . . . [the corresponding provisional application of Yu]" (Answer 5-6).[3]

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[3] There is some ambiguity on this record with regard to the exact sequence, identified by "SEQ ID NO", that is relied upon to establish the Examiner's prima facie case. Accordingly, we take a moment to clarify the nomenclature regarding Yu and the '285 provisional application. Yu teaches two proteins: DR3-VI and DR3. For DR3-VI, Yu teaches nucleic acid sequence (SEQ ID NO: 1) (Yu, col. 4, l. 67 – col. 5, l. 1) and protein sequence (SEQ ID NO: 2) (Yu, col. 4, ll. 56-57). For DR3, Yu teaches the nucleic acid sequence (SEQ ID NO: 3) and protein sequence (SEQ ID NO: 4) (Yu, col. 6, ll. 3-12). As Appellant explains, '285 only teaches the nucleic acid and protein sequences of DDCR (Br. 5), which Yu teach is the former name of DR3-VI (Yu, col. 5, ll. 59-62). '285 teaches that the isolated nucleic acid of DDCR (DR3-VI) has a sequence as set forth in SEQ ID NO: 1 ('285 10: 14-16), and the DDCR protein has the sequence as set forth in SEQ ID NO: 2 ('285 11: 8-26). While the Examiner initially refers to SEQ ID NO: 3 of Yu (Answer 4), the Examiner clarifies that in reality it is SEQ ID NOs: 1 and 2 of '285 that serve as the basis for the Examiner's prima facie case. As Appellant recognizes that '285 is the only disclosure that pre-dates Appellant's filing date (Br. 5) and directs attention to the DR3-VI sequence in '285 (Br. 5-10), we find that the Examiner's reference to SEQ ID NO: 3 in Yu is a harmless error and that Appellant had a fair opportunity to address, and in fact did address, the teachings in '285.

3. Page 67 of Yu's Provisional Application No. 60/013,285 ('285), filed March 12, 1996 "has support for the nucleic acid encoding the amino acid residues" set forth in Yu's patent (Answer 4).

4. A "sequence alignment provided with the Office action mailed on 10/07/2003" demonstrates that Yu's SEQ ID NO: 1 encodes a polypeptide comprising amino acid residues 25-198 of Appellant's SEQ ID NO: 6.

In response, Appellant asserts that:

A1. For the purposes of this appeal, the earliest effective filing date of the claimed subject matter is September 23, 1996 (Br. 5).

A2. Yu's '285 Provisional Application is the only application in Yu's lineage that "pre-dates the priority date currently accorded the pending claims" (*id.*).

A3. '285 only discloses a sequence for a polypeptide identified as DR3-V1 or DDCR (*id.*).

A4. DR3-V1 "does not correspond to the Apo-3 polypeptide in overall sequence or the particular regions identified in the present claims" (*id.*)[4].

A5. "the signal peptides of DR3-V1 and Apo-3 are very different when aligned from the first amino acid residue of each polypeptide" (Br. 6).

A6. "there is no indication in the '285 application that the deduced DR3-V1 polypeptide should be compared with other proteins, if at all, in any other way than from the first amino acid residue" (*id.*).

[4] We recognize Appellant's admission that "[t]he sequence the Appellant presented in the Appeal Brief appears to have omitted the Gln residue at position 25 and thus shifted the remaining residues on position" (Reply Br., third paragraph of "REMARKS" section).

A7. "no fragments having any likeness to the Apo-3 polypeptide of the present claims are identified in the '285 application" (Br. 8).

A8. the Examiner's "comparison of a segment of the deduced DR3-V1 polypeptide starting at amino acid position No. 36 with a portion of the Apo-3 polypeptide of the present claims" is "impermissibly based either on the knowledge of the sequence of the present claims or the disclosure from Yu . . . that was not included in the '285 application" (*id*).

A9. "The '285 application provides no indication that a region of the deduced DR3-VI polypeptide starting at amino acid position No. 36 exists as a separate polypeptide, begins a region of interest in the DR3-V1 polypeptide . . ., or has any significance whatsoever" (Br. 9).

We recognize, Appellant's discussion of their numbering convention (A4-A6 and A8) and assertion that Yu fails to identify or attribute a function to any particular region of their sequence that is defined by the amino acid residue numbers set forth in claim 34 (A7 and A9).[5] Nevertheless, we find that Appellant's concerns are misplaced. The issue is not whether Yu defines a fragment having a specifically defined function that corresponds to at least one of the specific regions set forth in claim 34, because the claims cover polypeptides which comprise these specific regions.

[5] We disagree with this assertion. '285 teaches that "[a]mino acids 1-30 constitute the signal peptide, amino acids 30-215 the ligand binding domain, amino acids 215-240 the transmembrane domain, amino acids 240-428 the intracellular domain, and amino acids 350-420 the death domain." The Examiner's focus in on the ligand binding domain.

Given the foregoing contentions of the Appellant and Examiner, we find the issue on appeal is two fold:

1. Does Yu teach an isolated nucleic acid that encodes a polypeptide that comprises an amino acid sequence that corresponds to any one of

   (a) 1 to 417,

   (b) 25 to 417,

   (c) 25 to 198, and

   (d) 338 to 417

   of SEQ ID NO: 6, or a biologically active variant thereof, and if so, does '285 support this teaching in Yu?
2. If so, does Yu disclose that this nucleic acid encodes a polypeptide that is Apo-3 or a biologically active variant thereof?

Issue 1:

We find that Yu teaches a nucleic acid sequence (SEQ ID NO: 1) that encodes a polypeptide (Yu, col. 4, l. 67 – col. 5, l. 1). Yu identifies the protein (SEQ ID NO: 2) encoded by the nucleic acid sequence set forth in SEQ ID NO: 1 as DD3-VI, formerly named DDCR (Yu, col. 4, ll. 56-57 and col. 5, ll. 59-62). We find that Yu's SEQ ID NO: 1 is the same as SEQ ID NO: 1 of '285. SEQ ID NO: 1 of both Yu and '285 teach an isolated nucleic acid encoding a polypeptide comprising amino acid residues (*see, e.g.*, '285 67: SEQ ID NO: 1, residues 36-198) that are identical to residues 25-198 of Appellant's SEQ ID NO: 6, or a biologically active variant thereof.

Therefore, issue 1 is answered in the affirmative.

Issue 2:

As discussed above, Appellant's claimed nucleic acid sequence encodes an Apo-3 polypeptide or a biologically active variant thereof that comprises one of four specifically defined amino acid residue ranges of SEQ ID NO: 6. Appellant defines an Apo-3 variant as "a biologically active Apo-3 as defined below having less than 100% sequence identity with Apo-3 having the deduced amino acid sequence shown in FIG. 4 (SEQ ID NO:6) for a full-length native sequence human Apo-3" (Specification 13: 32-35). Appellant defines "biologically active" as "having the ability to modulate apoptosis (either in an agonistic manner by inducing or stimulating apoptosis, or in an antagonistic manner by reducing or inhibiting apoptosis) in at least one type of mammalian cell in vivo or ex vivo" (Specification 19: 6-11). In addition, Appellant discloses that Apo-3 is believed to be a member of the tumor necrosis factor receptor family (Specification 8: 12-13).

Similarly, '285 teaches an isolated nucleic acid molecule (SEQ ID NO: 1), which is disclosed as "a novel member of the tumor necrosis factor (TNF) family of receptors" and comprises nucleic acid sequences encoding a death domain containing receptor (DDCR) ('285 3: 19-23). According to '285, the "death domain . . . is responsible for transducing signals for programmed cell death" ('285 3: 5-7). "Apoptosis, or programmed cell death, is a physiologic process essential to the normal development and homeostasis of multicellular organisms" (Yu, col. 2, ll. 22-24). As Yu explains, "[c]ellular response to TNF-family ligands include not only normal physiological responses, but also diseases associated with increased apoptosis or the inhibition of apoptosis" (Yu, col. 3, ll. 39-42). While the

polypeptide encoded by the sequence set forth in SEQ ID NO: 1 of '285 and Yu has less than 100% sequence identity with Appellant's claimed SEQ ID NO: 6, there is no evidence on this record that the nucleic acid taught by '285 and Yu, having SEQ ID NO: 1, does not encode a biologically active variant of Apo-3 as defined by Appellant's Specification.

Therefore, while '285 and Yu do not identify the polypeptide encoded by SEQ ID NO: 1 as Apo-3, both references describe the polypeptide in a manner that is consistent with the requirements of Appellant's claimed invention. Accordingly, absent evidence to the contrary, we find that the preponderance of the evidence on this record supports the conclusion that the nucleic acid set forth in '285 and Yu, having SEQ ID NO: 1, encodes a polypeptide that is a biologically active variant of Apo-3. Anticipation requires the disclosure, expressly or inherently, of all the limitations of a claimed invention in a prior art reference. *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.").

For the foregoing reasons we affirm the rejection of claim 34 under 35 U.S.C. § 102(e) as being anticipated by Yu. Since they were not separately grouped or argued, claims 36-39 fall together with claim 34. 37 C.F.R. § 41.37(c)(1)(vii).

CONCLUSION

In summary, we affirm the anticipation rejection of record.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

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